Minutes

Office of
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Biotechnology

Agricultural Biotechnology Research Advisory Committee

June 26, 1995

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October 1995

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE
Minutes of Meeting
June 26, 1995

Time, Place, and Participants

The U.S. Department of Agriculture (USDA) Agricultural Biotechnology Research Advisory Committee (ABRAC) met June 26, 1995, in the Club Room at the Westpark Hotel in Arlington, Virginia. The meeting had been announced in the Federal Register and was open to the public.

Members present included:

Walter A. Hill, Chair, Tuskegee University, Tuskegee, AL;
Anne Kapuscinski, University of Minnesota, St. Paul, MN;
Roy Fuchs, Monsanto Agricultural Company; St. Louis, MO;
H. Alan Wood, Boyce Thompson Institute for Plant Research, Ithaca, NY;
Fernando Osorio, University of Nebraska, Lincoln, NE;
Pamela Marrone, Agra Quest, Davis, CA;
Rudy Wodzinski, University of Central Florida, Orlando, FL,
Deborah Letourneau, University of California, Santa Cruz, CA,
Walter Reid, World Resources Institute, Washington, DC;
Stanley Pierce, Rivkin, Radler, & Kramer, Boca Raton, FL;
Paul Thompson, Yale University, New Haven, CT;
Robin Woo; Georgetown University, Washington, DC;
Alvin Young, Executive Secretary, ABRAC, and Director, USDA Office of Agricultural Biotechnology, Washington, DC.

USDA Office of Agricultural Biotechnology (OAB) staff members present included Daniel Jones, Jim Rasekh, and Marti Asner. Others present are listed in Appendix A.

Call to Order and Introductory Remarks

Dr. Hill called the meeting to order at 9:05 a.m. He introduced Dr. Robin Woo, a new member of the ABRAC, and asked the other ABRAC members and guests to introduce themselves. Dr. Young introduced the OAB staff members present.

Dr. Young noted that the scheduled speaker, Deputy Under Secretary of Agriculture for Research, Education, and Economics Floyd Horn, was unable to attend the meeting. However, Dr. Horn's office had sent a copy of his prepared remarks for Dr. Young to share with the ABRAC.

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Remarks by Deputy Under Secretary Horn

In his prepared remarks, Dr. Horn noted that the agricultural biotechnology landscape is changing rapidly, and that such changes make the ABRAC's advice more important than ever. ABRAC projects such as the voluntary performance standards for genetically modified fish and shellfish, and recommendations with respect to evaluating the food safety of transgenic animals are examples of significant contributions that the Committee has made.

Dr. Horn noted that when the ABRAC was chartered in 1988, then Secretary of Agriculture Richard Lyng suggested that a bioethicist be among the members. Dr. Horn also commended the ABRAC for recognizing that there are issues beyond those of science that will influence public acceptance of foods derived from biotechnology. He noted that this recognition was behind the ABRAC's participation in two USDA-sponsored symposia: one on the societal issues of food biotechnology in 1993 and one on animal biotechnology issues in 1994. Dr. Horn's remarks concluded by noting the challenges the ABRAC faced in its current agenda.

Performance Standards for Aquatic Research

Dr. Hill noted that the ABRAC, at its November 17, 1994 meeting, had endorsed the proposed performance standards for aquatic research. He then introduced Dr. Anne Kapuscinski, Chair of the ABRAC Working Group on Aquatic Biotechnology and Environmental Safety. Dr. Kapuscinski first reviewed the numerous points at which the public had contributed to development of the final draft of the standards before this final round of written comments. Then she summarized the written comments received on the final draft standards as follows.

Summary of Written Comments on Performance Standards

Dr. Kapuscinski reported that 15 comments on the performance standards had been received, 13 in support and 2 in opposition. Some of the supporting comments, while generally positive, expressed concern that the standards might result in the off-shore movement of research to countries that do not have such standards. Dr. Kapuscinski indicated that much of the international community, including a researcher from Cuba, had expressed the view that the standards would be helpful to research, rather than a hindrance. She noted that one of the opposing commenters had apparently not read the performance standards and the other expressed concern that the standards would lead to excessive regulation of research.

Based on the comments received, Dr. Kapuscinski enumerated the following as six recommendations to consider in revising the performance standards.

1. Revise the performance standards for genetically modified organisms that are also introduced species. This is intended to address concerns that the aquatic nuisance species protocol may not be appropriate for all introduced species situations. Instead, the flowcharts should direct the user to relevant Federal and State agencies for guidance and the supporting text should refer the reader to relevant biological principles described in publications on introduced aquatic species.

2. Revise flowchart IV.C on reproductive interference. Dr. Kapuscinski suggested adding the following question to the beginning of the chart:

"Is the group of GMO's sufficiently small relative to potentially interfered populations that estimated numbers of accidental escapees pose no appreciable risk of reproductive interference?"

If the answer is "yes," proceed to flowchart V. If the answer is "no" or unknown, proceed to the decision diamond at the top of the worksheet.

3. Clarify the pathway through the performance standards when initial information about the organism is insufficient. Dr. Kapuscinski recommended addition of the following paragraph to the explanation of Flowchart I:

"If the conclusion is that the standards do apply, researchers should proceed to subsequent flowcharts as directed. However, if preliminary perusal of the flowcharts indicates that researchers lack most of the required information, they may wish to proceed directly to flowchart VI.B, which guides risk management when there is insufficient information."

4. Revisit and/or revise the standards in the future. Dr. Kapuscinski suggested that a formal review of the computerized version of the standards be conducted after an agreed-upon period of time. Maryln Cordle, USDA (retired), suggested that an experience base be developed at the Federal-State workshops in order to facilitate future revisions of the standards. Dr. Young suggested that the standards be issued with a cover letter that includes a request for feedback.

5. Clarify the relationship of the performance standards to documentation required under the National Environmental Policy Act (NEPA). Dr. Kapuscinski suggested adding the following to the end of the paragraph on environmental safety on page 3:

"If approval or execution of the project is a Federal action requiring compliance with the National Environmental Policy Act, the completed worksheet (described below) could serve as the basis for NEPA documentation on environmental effects."

6. Address concerns about the effect of the performance standards on research. Dr. Kapuscinski suggested that the intentions of the standards be clarified by adding the following to the material on the purpose of the standards:

"By helping investigators to systematically address limited knowledge and manage risks, if any are identified, the performance standards are intended to expedite research and development involving genetically modified aquatic organisms. They are not intended to impede investigators from proceeding with such work."

ABRAC Comments on Performance Standard Recommendations

Dr. Osorio asked if a perception of over-regulation in the U.S. could cause the movement of aquaculture research to China. Dr. Kapuscinski replied that, in her view, movement of aquaculture research off-shore would be more likely in the absence of the performance standards because U.S. companies would be concerned about uncertainties of how to proceed with projects in the U.S. Dr. Eric Hallerman added that both the U.S. and China are world-leaders in aquaculture research.

Dr. Osorio asked if the implementation of the performance standards would include their adoption by regulatory agencies. Dr. Charles Brown, Animal and Plant Health Inspection Service (APHIS), replied that his agency has no plans to regulate transgenic fish research at this time. Dr. James Maryanski, Food and Drug Administration (FDA), drew a distinction betweeen activities for which research agencies are responsible and food safety regulation for which his agency is responsible.

Dr. Reid suggested that compliance with the standards be mandatory for those who seek USDA funding for their research. Dr. Kapuscinski emphasized the strong incentives that developers of the performance standards and other aquatic researchers have to comply voluntarily with the standards.

Dr. Osorio asked how much aquaculture research is funded by the U.S. government. Dr. Broussard replied that the total aquaculture research is around $50 million of which a little less than half is Federal and a little more than half is university-based and state funding.

Dr. Kapuscinski emphasized the importance of involving private aquaculture companies in the Federal/State workshops on the background and use of the performance standards.

ABRAC Recommendations on the Performance Standards

Dr. Hill invited ABRAC members to propose recommendations on follow-up activities concerning the performance standards.

1. Expert System on the Performance Standards

Dr. Letourneau moved that USDA develop a computerized expert system embodying the performance standards and make it available to the public. Dr. Osorio seconded.

Dr. Kapuscinski suggested that the expert system be distributed via the Internet for downloading by researchers and that a list-server be established to receive comments on user experience with the performance standards by electronic mail.

Dr. Wood expressed concern about the responsibility for maintaining a list-server. Dr. Kapuscinski suggested that the National Biological Impact Assessment Program (NBIAP) might be an appropriate organization to assume that responsibility. Dr. Wodzinski expressed concern about the cost of maintaining a list-server and the small number of people it would serve. Dr. Kapuscinski acknowledged that the on-line discussion of the standards could be deferred, but she remained committed to the on-line availability of the expert system. Dr. Pierce suggested that the details of distributing the expert system be left to USDA.

The ABRAC voted on Dr. Letourneau's motion for development of an expert system on the performance standards and approved it unanimously.

2. Video/Color Brochure on the Performance Standards

Dr. Marrone moved that USDA create a video to explain the performance standards to the public. Dr. Letourneau seconded.

Dr. Woo and Dr. Hill mentioned potential collaborators for production of a video including the USDA Extension Service and the University of Maryland biotechnology center. Dr. Eric Hallerman, Virginia Polytechnic Institute, suggested that a brochure with color photographs might be more cost effective than a video. Dr. Marrone amended her motion to include a color brochure as an alternative to a video.

The ABRAC voted on Dr. Marrone's motion to produce a video or a color brochure on the performance standards targeted at the general public and it passed unanimously.

3. Federal/State Workshops on the Performance Standards

Dr. Pierce moved that USDA sponsor a series of Federal/State workshops to introduce the *Performance Standards for Safely Conducting Research with Genetically Modified Fish and Shellfish*, to discuss how Federal and State agencies might integrate voluntary use of the standards with their own oversight programs, and to establish a partnership in collecting experience data on their effectiveness for future revisions. Dr. Letourneau seconded.

Dr. Thompson proposed an amendment to include economists in the workshops so that studies of the relative costs of complying with the performance standards would be part of the public record. Dr. Wood expressed the view that the financial and social costs of following the performance standards would be less than not following them. Dr. Thompson did not disagree, but he stressed the need for objective, socioeconomic research to support that view.

Dr. Charles Erikson, Food and Drug Administration, mentioned studies in addition to socioeconomics including environmental impacts and reductions in agricultural yields. Dr. Kapuscinski noted the growing complexity of research contemplated in the amendment. Dr. Pierce suggested that the amendment be considered on its own rather than as part of his motion. Dr. Thompson agreed to withdraw his amendment.

The ABRAC voted on Dr. Pierce's motion on Federal/State workshops and it passed unanimously.

4. Support for Aquacultural Biotechnology Research

Dr. Pierce put forward a second motion:

Now that the Performance Standards for Safely Conducting Research with Genetically Modified Fish and Shellfish are developed, ABRAC recommends that, to benefit the U.S. economy and consumers, USDA take all appropriate means to encourage and support biotechnology aquaculture research.

Dr. Marrone seconded and the ABRAC approved it unanimously.

5. Voluntary Nature of Performance Standards

Dr. Wood and Dr. Kapuscinski offered the following motion:

The ABRAC recommends that the Performance Standards for Safely Conducting Research with Genetically Modified Fish and Shellfish remain voluntary and that their utilization remain flexible enough that revisions can be easily incorporated. Dr. Wodzinski seconded.

Dr. Wood originally proposed that researchers seeking USDA funding for aquaculture research be required to use the standards. Dr. Broussard argued that linking the standards to USDA funding was contrary to assurances given to the research community while the standards were being developed. Dr. Wood subsequently withdrew the provision linking USDA funding with adherence to the standards, and he and Dr. Kapuscinski offered the motion shown above.

The ABRAC approved the motion on the voluntary nature of the performance standards by a vote of 11-1.

Conversion of Performance Standards to Computerized Expert System

Dr. Hill introduced Dr. Pat Traynor and Dr. Doug King of Virginia Polytechnic Institute and State University (Virginia Tech) who spoke to the ABRAC about how the standards could be converted to a computerized expert system.

Dr. Traynor explained that the NBIAP had awarded Virginia Tech a grant to develop expert systems for biotechnology. After talking with Dr. Young, she and Dr. King had developed a preliminary concept and a demonstration prototype for such a system.

Dr. King demonstrated some sample working code for an expert system (interactive text on a computer screen) based on a portion of the performance standards which included a multi-user file server, menu-driven logic, and hypertext capability. It operated under MS-DOS, but could be converted to a UNIX system if necessary. Conversion to a Macintosh operating system would, according to Dr. King, be difficult. Conversion to Windows could occur later but would add to the cost of the project. The system could be uploaded to the Internet as a compressed file that the user could download. Later, the system could be uploaded to the World Wide Web in HTML format, but that also would add to the cost of the project. It would be possible to add graphics, but doing so would increase the size of the file and possibly slow operation.

Dr. Letourneau suggested that the system include an overview feature at each significant point in the process so that the user could see where he or she was without having to refer to hard copy. Ms. Cordle suggested that the system be made available on CD-ROM.

Impacts of Large-Scale Planting of Transgenic Crops

Dr. Young recalled for the ABRAC that at its meeting in November, 1994, there were expressions of concern about the adequacy of data on the biological impacts of transgenic plants, particularly those planted in large-scale for commercial purposes. To help answer that question, Dr. Young introduced Dr. Jack Brown of the University of Idaho, who gave a presentation on the scientific criteria for assessing the biological impact of large-scale planting of transgenic crops.

Dr. Brown approached the subject through his own research on transgenic canola. Canola is a useful crop for examining biological impacts because of the acreage involved, 14 million acres in Canada and a lower but growing acreage in the United States due to the demand for low-fat cooking oils. In addition, canola was one of the first crop species to be genetically engineered for herbicide resistance. Some people have expressed two concerns about herbicide resistant crops. One is that the transgenic crop itself could become more weedy and the other is that the herbicide resistance gene could be transferred from the transgenic crop to weedy relatives.

Herbicide resistance in canola also presents an opportunity to develop a model that could help predict the biological effects of transgenic plants.
Dr. Brown and his team developed a theoretical model incorporating features for pollen movement, seed movement, reproductive compatibility, and hybrid fitness. He tested the model by planting herbicide-resistant canola in proximity to several wild relatives of canola including birdsrape mustard, wild mustard, and black mustard. Hybrid formation occurred and the response of the hybrids to herbicide application was determined.

Dr. Brown drew the following conclusions from the experiments he described:

Canola seeds are easily transported;
Canola pollen can move over distances greater than 24 meters, previously thought to be a natural limit;
Canola can hybridize with weedy relatives;
Bridge crosses influence gene movement; and
Hybrid plants may survive in nature.

Dr. Brown also identified the following questions for future research:

Can the model be adapted to other conditions?
Why do some crosses fail?
Is there a place for bridge crosses?
What is the fitness of a hybrid in nature?
How does gene movement occur in nature?
What steps should be taken when introduction of a transgenic variety takes place?

Dr. Brown concluded that future refinement of the transgenic canola model could help to place biotechnology risk assessment on a more scientific basis.

Dr. Letourneau commended Dr. Brown for collecting data on gene flow in canola. She considered canola to be a special case among agricultural crops because of its coexisting weedy relatives. She added that unintended transfer of herbicide resistance genes to weedy relatives could cause weed control efforts to backfire. Dr. Letourneau acknowledged that herbicide resistance might not increase the fitness of wild species under natural conditions, but that other traits, such as virus resistance, very likely could have that effect. She considered the lack of an apparent drop-off in pollen flow with distance to be an important result of Dr. Brown's experiments.

Dr. Fuchs also commended Dr. Brown for collecting gene flow data in canola. He noted that Dr. Brown's results were consistent with those of canola studies conducted by Dr. Keith Downey in Canada several years ago. Dr. Fuchs expressed support for a continued research focus on the nature of transferred traits, whether they can be transferred, whether they confer a selective advantage or disadvantage, and their impacts on the relative fitness of the recipient organism. He emphasized the importance of obtaining better scientific data on the factors that limit crop competitiveness and productivity. He concluded that a remaining question is how researchers can utilize the experience base from traditional breeding to improve predictions concerning the fate of transgenic traits.

Public Comments on Large-Scale Transgenic Plantings

Dr. Rasekh, OAB, asked whether the data from small-scale experiments could be incorporated into the model to make predictions about large-scale plantings. Dr. Brown replied that that was his intent.

Dr. Jane Rissler, Union of Concerned Scientists, suggested that risk research is not keeping pace with the drive toward commercialization of transgenic crops.

She advocated that a group of scientists, including plant ecologists, molecular biologists, and breeders be convened to discuss how to assess the risks of weediness and gene flow in transgenic crops.

Dr. Wodzinski asked if there are any viral, bacterial, or fungal pathogens that are effective against canola. Dr. Brown replied that he did not know of any viruses that have a commercial impact on canola.

Dr. Sally McCammon, USDA/APHIS, said that weediness, gene transfer, and other issues raised by Dr. Brown have been reviewed previously and agreed upon by a working group of the Organization for Economic Cooperation and Development (OECD).

Dr. Reid asked if past attempts at risk assessment of large-scale plantings have not been characterized by a shortage of data and assumptions of minimal risk. He contended that the kind of data collection exemplified by Dr. Brown's research may help to perform better assessments of the benefits as well as the risks of modified crops.

Dr. Rissler, Union of Concerned Scientists, questioned the practice of relying on conventional wisdom from traditional plant breeding when addressing potential impacts of transgenic plants. Instead, she advocated the collection of experimental data on transgenic plants themselves.

Dr. Payne, USDA/APHIS, responded that the bulk of experimental data collected confirms the conventional wisdom derived from plant breeding. He advocated more careful distinction between the context for risk assessment in managed and unmanaged ecosystems

ABRAC Discussion of Large-Scale Planting of Transgenic Crops

Dr. Woo, with assistance from Dr. Letourneau, Dr. Fuchs, and other ABRAC members, proposed the following three-part motion:

> To increase the public knowledge base on the actual environmental impact of transgenic plants, the ABRAC recommends that:
>
> 1. USDA channel funding from various sources, including a special provision in the Farm Bill, into basic research on environmental risk assessments of large-scale commercialization of transgenic plants.
>
> 2. USDA convene a workshop of experts from academia, government, and industry in the fields of ecology, molecular genetics, traditional plant breeding, the social sciences, and risk assessment to provide practical

technical advice for designing mechanisms and focusing research that will generate consistent data on the actual impact of newly commercialized transgenic plants.

3. USDA provide these expert recommendations to commercial producers and encourage them to incorporate these recommendations voluntarily when they assess the environmental impacts of new transgenic products at the early stages of commercialization, and to share their data with the scientific community.

Members discussed the collection and availability of monitoring data on large-scale plantings of transgenic crops. Dr. Fuchs indicated that companies routinely monitor large-scale plantings for agronomic performance as well as ecological impacts, the latter often in cooperation with academic colleagues. Dr. Marrone noted the reluctance of companies to release monitoring data perceived as "negative." Dr. Rissler, Union of Concerned Scientists, contended that monitoring data is not as readily available from either government or industry as many people claim. Dr. Payne, USDA/APHIS, distinguished between company data claimed as confidential for which requests may be evaluated under freedom of information procedures, and other data in electronic format which is freely available.

Dr. Hill deferred immediate action on Dr. Woo's motion to allow time for Dr. Neven's presentation. At a later point in the meeting, the ABRAC approved Dr. Woo's motion unanimously.

Genetically Modified Insects

Dr. Young introduced Dr. Lisa Neven, USDA Agricultural Research Service, Yakima, Washington, who spoke on "Genetically Modified Insects: What to Expect from the Research Community."

Dr. Neven reported that insect species which have been genetically modified include fruit fly, Mediterranean flour moth, silk moth, mosquitoes, pink bollworm, honeybee, Medfly, melon fly, Oriental fruit fly, parasitic wasps, tobacco budworm, Indian meal moth, beet armyworm, cabbage looper, red flour beetle, boll weevil, and cotton bollworm. Much of this research, she said, takes place in USDA laboratories.

Dr. Neven indicated that the objectives of genetic transformation of insects include mutation analysis, behavioral and genetic analysis, determination of vector competence, elucidation of developmental physiology, improvement of autocidal biological control, analysis of chemical resistance mechanisms, analysis of hybrid sterility, and pre-determination of gender.

The types of genes used to modify insects, according to Dr. Neven, include transposable elements, marker genes, antibiotic resistance genes, pesticide resistance genes, silk proteins, disease resistance genes, and conditional lethal genes that are inducible.

The agencies involved in this work include the National Institutes of Health (NIH), the U.S. Centers for Disease Control (CDC), APHIS, ARS, and the International Atomic Energy Association. In addition, public and private universities, private research institutions, and biotechnology companies are involved in this work. Dr. Neven reported that literally hundreds of laboratories in the U.S. and throughout the world are working with transgenic insects. She distinguished between "transgenic" meaning containing a foreign gene and "genetically modified" which could include techniques such as radiation induced mutation.

Dr. Neven described her personal path of discovery concerning the number of parties she was expected to inform of her research. These included her research leader, her local Institutional Biosafety Committee (IBC), the granting agency, and her State's department of agriculture. She reported that her state department of agriculture did not understand what she was doing and could not determine the proper forms to send her. She also found that many USDA scientists do not believe they are expected to tell anyone other than their supervisor about their research. Finally, she found it difficult to find out who needed to be informed about her project.

Dr. Neven also reported that she could find no biosafety regulations or other guidelines with respect to transgenic insects other than those provided by NIH for *Drosophila*. Moreover, most laboratories do not have the secured facilities necessary to conduct experiments that involve such insects. She said her institution was very fortunate to have a BL-2 secured laboratory facility for handling insects. Dr. Neven affirmed her wish to perform her research in a proper, ethical, and safe manner with adequate notification and approval, if necessary, of the appropriate authorities.

ABRAC Discussion of Transgenic Insect Research

Dr. Marrone distinguished three general areas of insect research: 1) basic research on the genetics, biology, and population dynamics of insects; 2) manipulating insects for use in pest control/management; and 3) improving beneficial insects to be hardier, more disease and pesticide resistant, etc.

Dr. Marrone expressed concern that there is no consistent framework or containment guidelines for conducting research with transgenic insects

considering the amount of work that is apparently ongoing. She also expressed concern that some researchers are apparently not informing their institutional biosafety committees or state agencies of their research.

Dr. Reid expressed concern about the adequacy of the brief breeding history of insects as a basis for risk analysis, their high potential for geographic dispersal, and the current minimal ecological knowledge of insects. Those conditions, said Dr. Reid, combined with the apparent lack of oversight, guidance, and familiarity of researchers with environmental safety requirements leave a procedural gap of some concern.

Dr. Wood pointed out that USDA requires that research grant applications involving recombinant DNA have the approval of the local institutional biosafety committee and that many states have similar requirements. He expressed the view that the provisions for transgenic animals in the NIH Guidelines cover all the relevant issues.

Dr. Pierce advocated the development of performance standards for transgenic insects along the lines of those just completed for genetically modified fish and shellfish.

Dr. Kapuscinski asked what kind of oversight exists for a researcher who wishes to test a transgenic insect outside a contained laboratory.

Dr. Payne, USDA/APHIS, replied that there is a full regulatory process in place for transgenic insects. Taking insects to the field, he said, requires an APHIS permit under 7 CFR 340 in the same way that transgenic plants and many microorganisms are regulated under the Federal Plant Pest Act. Exceptions may include mosquitos and other human or animal disease vectors which may be subject to requirements of the U.S. Centers for Disease Control.

Dr. Kapuscinski referred to the perception that the NIH Guidelines and Appendix Q are so general with respect to insects that it is difficult, in many cases, to figure out how they would apply. She echoed Dr. Pierce in suggesting the development of insect-tailored, scientific criteria similar to the aquatic performance standards which she believed could be of value not only in moving insect research forward, but also a valuable supplement to the information in APHIS permit application forms.

Dr. Payne expressed doubt that a general look at criteria for insect research would be the best use of the Committee's time. He referred to his previous frustration in working with the National Institutes of Health (NIH) on Appendices P and Q of the NIH Guidelines.

Dr. Letourneau expressed frustration in waiting for the first insect release application to arrive before doing anything. She asked if it is not time to develop scientific guidance on what kinds of data researchers should collect in order to properly address scientific issues associated with perceived barriers to moving forward with insect research.

Dr. Payne expressed the view that the problem is fear of the regulatory process. He referred to Dr. Marjorie Hoy, University of Florida, whose research on transgenic insects could be in the field now but isn't. He viewed the development of scientific guidance as a "stop and study" exercise that would in itself constitute a barrier to promising applications of modified insects in agriculture. He acknowledged that the aquatic performance standards filled a void in the legal and regulatory oversight of aquatic research. But he denied that such a void exists for transgenic insect research and development.

Dr. Marrone drew parallels with early work on modified plants and fish in which environmental assessments were done on a case-specific basis. She expressed concern that continued adherence to the case-by-case approach would impede research. She said that Dr. Hoy at the University of Florida does not wish her research to be the first to traverse the regulatory process without the benefit of scientific guidance or precedent. Dr. Marrone argued that research and field release could be accelerated by clear and adequate performance standards or guidelines for groups of organisms such as insects that have biological traits and risk factors in common.

Dr. Fuchs suggested that fully developed performance standards may not be necessary as long as the scientific community identifies for USDA scientific issues that need to be resolved.

Dr. Neven mentioned that both she and her State Department of Agriculture found the forms for movement of insects and transgenic plants to be inaccurate, confusing, and generally not helpful.

Dr. Payne acknowledged that APHIS needs to have more discussion with State Departments of Agriculture concerning insects. He argued, however, that the case-by-case approach builds on experience and expert knowledge of specific biological systems. He claimed that general guidelines are not science and that they "are only of value to make everybody feel good."

Dr. Kapuscinski reminded the Committee that the performance standards for fish and shellfish do much more than make people feel good. She said they are both scientifically based and flexible enough to be case specific. The case specificity, she said, arises from the carefully chosen order of questions in the decision framework which allows researchers to bypass large sections of the

performance standards when appropriate for their particular application. She reiterated that performance standards for insects would be of immense value to pioneering researchers like Marjorie Hoy and could also be of value to regulatory agencies like APHIS. Dr. Kapuscinski recognized the legal and regulatory difference between the fish and insect areas, but she viewed it as a separate issue from providing appropriate and transparent scientific guidance to the people who would really like to have it.

Dr. Rissler, Union of Concerned Scientists, argued that transparency, as exemplified by the fish guidelines, is very important to public trust. She also expressed support for convening a group of experts to address the risks of transgenic insects.

ABRAC Recommendation on Transgenic Insects

Dr. Marrone offered the following preamble to a motion:

Valuable research and field release could be accelerated by a clear and adequate framework for transgenic arthropod work. The ABRAC is concerned that transgenic arthropod research may be progressing without this clear guidance on risk assessment and risk management.

Dr. Marrone proposed the following motion and Dr. Kapuscinski seconded:

The ABRAC recommends that an ABRAC working group be formed to develop a clear scientific framework for research and field release of transgenic arthropods.

In Committee discussion, Dr. Wood argued that the motion is unnecessary, because NIH already has the mechanisms to regulate research on such insects. Ms. Cordle recalled that during the development of the fish performance standards, NIH was not receptive to increasing the specificity of its guidelines to encompass fish. This resulted in casting the performance standards for fish as an elaboration of the general principles of the NIH Guidelines.

After additional discussion, the motion was adopted by a vote of 10-2.

Dr. Young said that he would forward the recommendation to the appropriate officials at USDA and inform the ABRAC of the Department's decision.

Updates and Other Business

Dr. Young reported that the Administration's Biotechnology Research Subcommittee (BRS) will shortly issue a report to which the ABRAC had some

input entitled *Biotechnology for the 21st Century: New Horizons*. Ray Dobert of the USDA's National Agricultural Library said he was working with the BRS to produce an electronic version of the report that would be accessible on the Internet.

Dr. Thompson reported that the National Science Foundation recently issued a report entitled *Science, Technology, and Democracy: Research on Issues of Governance and Change*. The report contains, among other things, a suggestion on how to co-fund socioeconomic research along with scientific research through a grant rider mechanism. Dr. Thompson invited members of the ABRAC and the public to submit comments to him or Dr. Young on how agricultural biotechnology could be synergized with some of the topics outlined in the report. He asked that comments be sent to:

Dr. Paul Thompson
Center for Biotechnology Policy
Texas A&M University
College Station, TX 77843-4355
Telephone: (409) 845-5434
E-mail: pault@tam2000.tamu.edu

Dr. Young suggested October or November as a tentative time for the next meeting.

Dr. Hill adjourned the meeting at 4:48 p.m.

Approved:

SUSAN McCULLOUGH
Rapporteur

DANIEL JONES
Editor

ALVIN YOUNG
Executive Secretary

WALTER HILL
Chair

LIST OF VISITORS
U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE
Arlington, Virginia
June 26, 1995

Lisa Neven, Agricultural Research Service, USDA
Jack Brown, University of Idaho
Charles E. Erickson, III, U.S. Food and Drug Administration
Mari Trossing, Embassy of Sweden

Pat Traynor, Virginia Polytechnic Institute and State University
Doug King, National Biological Impact Assessment Program
Linda Murphy, American Society of Microbiology
Jay Blowers, National Biological Impact Assessment Program

Margriet Caswell, Economic Research Service, USDA
Jim Maryanski, U.S. Food and Drug Administration
Meryl Broussard, Cooperative State Research, Education, and Extension Service, USDA
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Anne Marie McNamara, Food Safety and Inspection Service, USDA
Ray Dobert, National Agricultural Library, USDA

Bette Hileman, Chemical Engineering News
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